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Review of Chemistry, Manufacturing and Control issues for rhIL-11

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Sponsor:	Genetics Institute
Product:	Oprelvekin (rhIL-11, Neumega®)
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I. Introduction

The manufacturer, Genetics Institute, seeks approval for oprelvekin (Neumega®, rhIL-11) for the prevention of chemotherapy-induced thrombocytopenia. This review focuses on CMC issues. Support of a license for oprelvekin is based on the FDA's Guidance Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products [60 FR 35750 7/11/95]. This document provides the opportunity for a licensing application to be submitted based upon data obtained from a product manufactured in a pilot facility when licensure of that product and facility is not sought. In this licensing scenario, the application should include a description of all manufacturing changes, data demonstrating product comparability between product manufactured in the pilot facility and product manufactured in the new facility, stability data, a demonstration of product consistency of the product manufactured in the new facility, and process validation data.

IL-I 1 is a thrombopoietic growth factor that stimulates the production of hematopoietic stem cells and megakaryocyte progenitor cells resulting in increased platelet production. Recombinant human IL-I 1 (rhIL-11) is synthesized in E. *Coli* [

8 lines

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[

1 Figure

(b)(4)

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II. Production

A. Construction and characterization **of the plasmid.**

1. Background

(b)(4) IL-1 1 activity was first identified in the conditioned medium of an immortalized non-human primate (adult macaque) stromal cell line [~] which supported the growth of the IL-6-, dependent murine plasmacytoma cell line [~] in the presence of a neutralizing antiserum against hIL-6. [

4 lines

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